FLINT WATER CASE

Bone Lead Assessment - Second Site Goals

- increase access to bone lead assessment to all Flint residents
- replicate protocols of existing site (Napoli/Specht/Weitzman) so outcomes are consistent

Anticipated Steps

Step 1a: Meet with Specht.

Step 1b: Acquire written details of Specht's protocol regarding how the XRF device is customized; how each test is performed; how the device is calibrated; how the spectra are analyzed. Replicate waivers/consent that Flint residents sign.

Step 2: Establish funding mechanism to set up a second site. Establish contracts, approvals, and oversight mechanism.

- Estimated costs of Flint site: approximately \$550,000 through Aug 26 (w/out facility fees)
- Estimated costs of analysis: approximately \$50,000 through Aug 26

Step 3: Meet with compliance authorities to lay out regulatory requirements needed to conduct this assessment. Acquire all approvals, as needed. Establish and approve waivers/consents.

Step 4: Purchase Niton XRF device from Thermo; customize it; confirm the device is working properly. Register the device in State of MI

Step 5: Conduct safety assessment of the XRF device for subject and operator (dosimetry tests)

Step 6: Acquire facility to conduct assessments (site approvals, access; COVID safety; privacy; security; secure wifi, ...)

Step 7: Identify physician willing to participate and sign off on assessments

Step 8: Establish and approve protocol for the bone lead assessment process –scheduling, access to site, COVID safety, XRF safety, privacy, calibration, analysis, reporting. Confirm physician approval of protocols and entire workflow.

Step 9: Hire individuals (eg, nurses) to execute protocol

Step 10: Establish scheduling technology and execute communication campaign regarding second site availability

Step 11: Open site and execute assessments according to protocol. Document assessments. Conduct periodic safety tests, (eg, leak tests) and document.

Step 12: Analyze spectra in timely manner. Contact individuals with bad spectra for return visit. Report outcomes.

Step 13: Compare mean and standard deviation of assessments between Specht and UofM groups of participants.

